CLAIMS

1. Process for the processing of information used for the management of quality in a therapeutic process, this therapeutic process comprising the operations of taking cells (PR) from a patient (PA), specific treatment operations on these cells using a specific treatment protocol, and a reinjection operation into the patient of said cells treated in this way, these operations of taking cells, treatment and reinjection being subjected to a standard operating procedure for preparation (SOP) comprising a series of functional stages,
characterized in that it comprises, for each batch of samples taken from a given patient:
- for each functional stage, a stage of sequential and conditional validation (VA) of said stage, the passing from one validation stage to the following validation stage being conditional on the results of the processing of data collected during this validation stage, and
- a stage of processing of the information and data collected in the different validation stages, in order to issue final certification (CF) of a preparation carried out according to the standard operating procedure and/or a list of the anomalies detected during this preparation.

2. Process according to claim 1, characterized in that validation of the final certification is conditional on the input of a validation password.

3. Process according to one claims 1 or 2, implemented in a data processing system, characterized in that with each validation stage is associated at least one screen page (PO, Pei, EP, EA, EC, EI) which can be accessed on the display means of at least one workstation connected to said data processing system.

4. Process according to claim 3, characterized in that each

screen page comprises a coded identification field for a patient which matches the batch of samples subjected to the standard operating procedure.

5. Process according to any one of the previous claims, characterized in that the exit from certain stages (RA) of said process is conditional on printing the screen pages (EA) corresponding to these stages.

6. Process according to any one of the previous claims, implemented in a preparation laboratory receiving therapeutic kits from at least one operational entity (EX), characterized in that it further comprises stages for monitoring the transfer of these kits.

7. Process according to any one of the previous claims, implemented in a preparation laboratory which deals with a cytapheresis service, characterized in that it further comprises stages for monitoring the receipt of cytapheresis pouches.

8. Process according to any one of the previous claims, implemented in a preparation laboratory which deals with a control laboratory, in particular a bacteriological control laboratory, characterized in that it further comprises stages for processing the results of control tests carried out on each batch of samples.

9. System for the processing of information used for the management of quality in a therapeutic process, this therapeutic process comprising the operations of taking cells (PR) from a patient (PA), specific treatment operations on these cells using a specific treatment protocol (SOP), and a reinjection operation (RI) into the patient of said cells treated in this way, these operations of taking cells, treatment and reinjection being subjected to a standard operating procedure for preparation comprising a series of

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functional stages (TR),
characterized in that it comprises, for each batch of samples taken from a given patient:

- for each functional stage, a means of sequential and conditional validation (VA) of said stage, the passing from one validation stage to the following validation stage being conditional on the results of the processing of data collected during this validation stage, and
- a means of processing of the information and data collected in the different validation stages, in order to issue final certification (CF) of a preparation carried out according to the standard operating procedure and/or a list of the anomalies detected during the preparation.

10. System according to claim 9, implemented in a preparation laboratory, characterized in that it is further designed to execute management tasks (GN) within this laboratory.

11. System according to claim 9, characterized in that it is connected to a communications network in order to exchange data with other entities (CTn, Ln, Cyn, CRn, CB) involved in a therapeutic process.

12. Application of the process and of the information processing system used for quality management according to any one of the previous claims to cell therapy protocols.

13. Application of the process and of the information processing system used for quality management according to any one of the previous claims to gene therapy protocols.

14. Application of the process and of the quality management system according to any one of the previous claims, allowing ongoing training of the operator and/or the monitoring of his or her level of knowledge.